WHAT IS CLAIMED IS:

424/472, 473

1. A pharmaceutical composition in unit dosage form for both intraoral and oral administration to a patient, said unit dosage form configured to be placed within the mouth of said patient, which comprises:

(a) as a first portion, at least one discrete outer layer comprising a therapeutically effective amount of at least one pharmaceutically active ingredient capable of intraoral administration; and

(b) as a second portion located within said first portion, a therapeutically effective amount of at least one pharmaceutically active ingredient capable of oral administration and which is releasable and orally ingestible by the patient after the outer layer has disintegrated or has dissolved intraorally.

2. The pharmaceutical composition defined in claim 1 in the form of a tablet or capsule. 451 463

3. The pharmaceutical composition defined in claim 2 wherein the unit dosage form is a tablet and the second portion of the composition is an inner core or at least one layer of a

multi-layer tablet, and the first portion is either an outer coating applied on the core or is one or more of the outer layers of a multi-layer tablet.

4. The pharmaceutical composition defined in claim 2 wherein the unit dosage form is a capsule and the second portion of the composition is an uncoated capsule including the pharmaceutically active ingredient capable of oral administration on which the first portion is applied as an outer layer forming an outer coating.

5. The pharmaceutical composition defined in claim 3 wherein the outer coating is a film coat that is applied as a layer to the inner core.

6. The pharmaceutical composition defined in claim 3 wherein the outer coating is a compression coat that is compressed around the inner core.

7. The pharmaceutical composition defined in claim 5 wherein the film coat comprises the at least one pharmaceutically active ingredient capable of intraoral administration and at least one pharmaceutically acceptable coating polymer selected

from the group consisting of cellulose, hydroxypropyl methylcellulose, methyl cellulose, polyvinylpyrrolidone, and polyethylene glycol, a pharmaceutically acceptable plasticizer, a pharmaceutically acceptable glidant and a pharmaceutically acceptable colorant.

8. The pharmaceutical composition defined in claim 6 wherein the compression coat comprises the at least one pharmaceutically active ingredient capable of intraoral administration and at least one pharmaceutically acceptable excipient for intraoral administration of the pharmaceutically active ingredient.

9. The pharmaceutical composition defined in claim 6 wherein the compression coat comprises the at least one pharmaceutically active ingredient capable of intraoral administration formulated in a pharmaceutically acceptable effervescent agent which generates effervescence when contacted with salivary fluid.

10. The pharmaceutical composition defined in claim 3 wherein the first portion comprises one or two outer layers each comprising a therapeutically effective amount of at least one

pharmaceutically active ingredient capable of intraoral administration and one or more pharmaceutically acceptable excipients for intraoral administration of the pharmaceutically active ingredient capable of intraoral administration.

11. The pharmaceutical composition defined in claim 3 wherein the outer layer of the multi-layer tablet is formulated with a pharmaceutically acceptable effervescent agent which generates effervescence when contacted with salivary fluid.

12. The pharmaceutical composition defined in claim 7 wherein the film coat further comprises a pharmaceutically acceptable flavoring agent.

13. The pharmaceutical composition defined in claim 3 wherein the inner core is an immediate drug release tablet comprising the pharmaceutically active ingredient capable of oral administration and at least one pharmaceutically acceptable excipient for oral administration of the pharmaceutically active ingredient capable of oral administration.

14. The pharmaceutical composition defined in claim 3 wherein the inner core is in a configuration which provides

sustained release of the pharmaceutically active ingredient capable of oral administration and which further provides an immediate drug release layer tablet comprising the pharmaceutically active ingredient capable of oral administration and at least one pharmaceutically acceptable excipient for oral administration of the pharmaceutically active ingredient capable of oral administration.

15. The pharmaceutical composition defined in claim 3 wherein the second portion is the at least one layer of the multi-layer tablet comprising the pharmaceutically active ingredient capable of oral administration and which is an immediate drug release layer.

16. The pharmaceutical composition defined in claim 3 wherein the second portion is the at least one inner layer and provides sustained release of the pharmaceutically active ingredient suitable for oral administration over a period of 0.5 to 24 hours.

17. The pharmaceutical composition defined in claim 3 wherein a delayed release coating covers the inner core and comprises the second portion of the composition and then the

first portion of the composition is an outer layer over the delayed release coating to delay release of the pharmaceutically active ingredient capable of oral administration for a period of 0.5 to 12 hours.

18. The pharmaceutical composition defined in claim 17 wherein the delayed release coating comprises one or more pharmaceutically acceptable polymer selected from the group consisting of methyl cellulose, hydroxypropyl cellulose, hydroxyethyl cellulose, hydroxymethyl cellulose, hydroxypropyl methyl cellulose acetate succinate, ethyl cellulose, cellulose acetate phthalate, hydroxypropyl methylcellulose phthalate, cellulose acetate trimellitate, carboxymethylcellulose sodium, acrylic acid polymers and copolymers, polymers or copolymers of methacrylic acid, methyl acrylate, ethyl acrylate, methyl methacrylate, ethyl methacrylate, vinyl acetate, vinyl acetate phthalate, or an azo compound, polyvinyl pyrrolidone, pectin, amylose, shellac, zein, and guar gum.

19. The pharmaceutical composition defined in claim 3 wherein the inner core or a layer of the multi-layer tablet core is chewable and comprises at least one pharmaceutically

acceptable excipient suitable for a chewable medication and a flavoring agent.

20. The pharmaceutical composition defined in claim 4 wherein the film coat comprises the pharmaceutically active ingredient capable of intraoral administration and at least one pharmaceutically acceptable coating polymer selected from the group consisting of cellulose, hydroxypropyl methylcellulose, methyl cellulose, polyvinylpyrrolidone, and polyethylene glycol, a pharmaceutically acceptable plasticizer, a pharmaceutically acceptable glidant, a pharmaceutically acceptable colorant, and optionally a pharmaceutically acceptable flavoring agent.

21. The pharmaceutical composition defined in claim 4 wherein the second portion of the composition is a capsule containing the pharmaceutically active ingredient capable of oral administration and a pharmaceutically acceptable excipient for sustained release of the pharmaceutically active ingredient suitable for oral administration to provide a sustained release effect of the pharmaceutically active ingredient for 0.5 to 24 hours.

22. The pharmaceutical composition defined in claim 1 wherein the outer layer disintegrates or dissolves within 10 minutes permitting release of the pharmaceutically active ingredient capable of intraoral administration, when the composition is contacted with saliva during intraoral administration.

23. The pharmaceutical composition defined in claim 22 wherein the second part of the composition containing the pharmaceutically active ingredient capable of oral administration remains intact until the intraoral administration of the pharmaceutically active ingredient capable of intraoral administration has been completed.

24. The pharmaceutical composition defined in claim 22 wherein the outer layer disintegrates immediately to allow a rapid intraoral mucosal absorption of the pharmaceutically active ingredient capable of intraoral administration released from the outer layer.

25. The pharmaceutical composition defined in claim 1 which further comprises a pharmaceutically acceptable signalling system located between the first portion and second portion of

the composition, within the first portion of the composition or within the second portion of the composition and that is detectable by the patient upon substantial release of the pharmaceutically active ingredient capable of intraoral administration during intraoral administration thereby informing the patient that it is time to orally ingest the remaining second part of the composition containing the pharmaceutically active ingredient capable of oral administration.

26. The pharmaceutical composition defined in claim 1 wherein the pharmaceutically active ingredient capable of intraoral administration has a first pass metabolism which is avoided by intraoral administration.

27. The pharmaceutical composition defined in claim 1 wherein the pharmaceutically active ingredient capable of intraoral administration has a rapid onset of desired therapeutic effect through intraoral absorption.

28. The pharmaceutical composition defined in claim 1 wherein the pharmaceutically active ingredient capable of intraoral administration is selected from the group consisting of analgesics, antihistamines, antidiarrheals, anxiolytics,

hypnotics, stimulants, cardiovascular drugs, pulmonary drugs, anti-hypertensives, anti-emetics, anti-inflammatory drugs, renal drugs, steroids, drugs for neurological disorders, anti-psychotic drugs, drugs for treating endocrine disorders, drugs for promoting immunology, drugs for treating osteoarthritis, drugs for treating glaucoma, drugs for treating allergic rhinitis, drugs for treating anemias and other hematological disorders, drugs for treating infectious diseases, drugs for the treatment and symptoms of cancer, drugs for insomnia, and antidiabetic drugs.

29. A process for the preparation of a pharmaceutical composition in unit dosage form as a tablet or capsule for both intraoral and oral administration to a patient, said pharmaceutical composition placed within the mouth of said patient, which comprises:

(a) as a first portion, at least one discrete outer layer comprising a therapeutically effective amount of at least one pharmaceutically active ingredient capable of intraoral administration; and

(b) as a second portion located within said first portion, a therapeutically effective amount of at least one pharmaceutically active ingredient capable of oral administration

and which is releasable and orally ingestible by the patient after the at least one outer layer has disintegrated or has dissolved within the patient's mouth which comprises the steps of:

(i) providing the second portion as an inner tablet core or as at least one layer of a multi-layer tablet core or as an uncoated capsule; and

(ii) applying the first portion as an outer layer or as several outer layers forming an outer coating on the first portion.

30. A method of administering a pharmaceutical composition in unit dosage form as a tablet or capsule for both intraoral and oral administration to a patient, which comprises:

(a) as a first portion, a discrete outer layer comprising a therapeutically effective amount of at least one pharmaceutically active ingredient capable of intraoral administration which provides a rapid onset of a desired therapeutic effect; and

(b) as a second portion located within said first portion, a therapeutically effective amount of at least one pharmaceutically active ingredient capable of oral administration and which is releasable and orally ingestible by the patient

after the outer layer has disintegrated or has dissolved under the patient's tongue or elsewhere within the patient's mouth, which comprises the steps of:

(i) placing the pharmaceutical composition under the tongue, against the inner wall of the cheek or the upper or lower vestibular layer or elsewhere within the mouth of said patient;

(ii) retaining the pharmaceutical composition under the tongue or against the inner wall of the cheek or the upper or lower vestibular area or elsewhere within the mouth of the patient until the first portion of the pharmaceutical composition containing the pharmaceutically active ingredient capable of intraoral administration has dissolved or has disintegrated thereby substantially releasing the pharmaceutically active ingredient capable of intraoral administration; and

(iii) following step (ii) swallowing whole or chewing and swallowing the second portion of the pharmaceutical composition.

presence or absence

31. The method of administering a pharmaceutical composition defined in claim 30 wherein the pharmaceutical composition further comprises a pharmaceutically acceptable signalling system located between the first portion and second portion of the composition, within the first portion of the

composition or within the second portion of the composition and which following step (ii) further comprises the step of relating a signal from the signalling system to indicate to the patient substantial release of the pharmaceutically active ingredient capable of intraoral administration during intraoral administration in step (ii) thereby informing the patient that it is time to orally ingest the remaining second part of the composition containing the pharmaceutically active ingredient capable of oral administration according to step (iii).

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